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Jan Johan Hendrik Smit

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EXAMINER

DANIELS, MATTHEW J

ART UNIT

PAPER NUMBER

1791

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/804,738	<b>Applicant(s)</b> SMIT, JAN JOHAN HENDRIK	
	<b>Examiner</b> MATTHEW J. DANIELS	<b>Art Unit</b> 1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6 and 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

1. The declaration filed on 17 January 2008 under 37 CFR 1.131 has been considered but is ineffective to overcome the Bellin reference for the following reasons:

(1) The declaration does not state where the prior invention occurred. While the inventor declares citizenship, this does not establish that the prior invention occurred in the United States, a NAFTA country, or a WTO member country. Prior invention may not be established prior to certain dates in NAFTA or WTO countries, and the instant declaration does not state that the date of conception falls within the window permitted by 37 CFR 1.131.

(2) It is unclear whether the declaration is meant to establish reduction to practice prior to the effective date of the invention, or conception prior to the effective date of the invention coupled with diligence. The statements “a fax” (Smit Decl. ¶ 2) and “the fax” (Smit Decl. ¶ 3) rely on the same piece of evidence to establish prior conception and diligence. Also see the “second Dutch language letter” (Smit Decl. ¶ 2, ¶ 3). If relied upon for conception, then it is the Examiner’s position that the evidence does not provide evidence of prior conception of the claimed *method*. It is also unpersuasive as evidence of diligence because it does not take place during the critical period.

(3) The character and weight of the evidence provided with the declaration is insufficient to show conception of the claimed invention. The declaration does not appear to show any conception or reduction to practice of the claimed *method*. The claimed method is defined by a number of particularly claimed steps. Evidence that a machine existed which had the capability

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to be operated in the claimed manner does not provide evidence that the Inventor conceived or actually used the machine to practice the claimed method.

(4) The character and weight of the evidence provided with the declaration is insufficient to show diligence. In making this determination, it is noted that there is no evidence of any activity or explanation for the period from or immediately preceding December 1, 1999 through April 24, 2000 (approximately 4.5 months). There is no evidence of any activity or explanation for a second period from June 27, 2000 through July 14, 2000 (approximately 1.5 months).

In view of the foregoing and the fact that the factual and legal basis of the rejection over Bellin is undisputed, the rejection is maintained.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. **Claim 6** is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bellin (USPN 6692527). **As to Claim 6**, this claim recites “topside” and “partly immersed”. In a first interpretation of the term “topside”, the topside is the flattened portion of the mold which forms the portion of the implant to be placed against the patient’s chest. This interpretation is supported by Fig. 2, items 13, which appear to have a

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rounded portion facing upwards. A flattened portion appears to face the dipping bath. In a first interpretation of the term “partly immersed”, the phrase has been interpreted as “immersed”.

This interpretation is consistent with the specification at page 4, lines 22-35, which states that the angle of the arm which holds the mold allows the upper end of the mold to be dipped in the plastic solution before the entire mold disappears in the solution. Therefore, the immersing appears to be a continuous process, wherein a portion of the mold is partly immersed before subsequently immersing the whole mold.

In this first interpretation under 35 USC 102(e), Bellin teaches a method for manufacturing a silicone cover (6:8), or article which could be used as a cover, for a breast implant (4:15-67, 2:8-50), wherein a mould for this cover (Fig. 4A) is repeatedly dipped in a plastic solution (2:51-67), and after repeated dipping of the mould (2:51-67), at least one curing treatment takes place (2:59, 6:43-50) wherein prior to said repeated dipping the mould is partly immersed in the plastic solution such as to first allow a topside of the mould to come in contact with the solution (2:51-67).

In a second interpretation of the term “partly immersed”, the term is interpreted to mean that the form is only partially immersed to coat only a portion of the article or form. In this second interpretation under 35 USC 102(e), Bellin teaches a method for manufacturing a silicone cover (6:8), or article which could be used as a cover, for a breast implant (4:15-67, 2:8-50), wherein a mould for this cover (Fig. 4A) is repeatedly dipped in a plastic solution (2:51-67), and after repeated dipping of the mould (6:1-26), at least one curing treatment takes place (2:59, 6:43-50) wherein prior to said repeated dipping the mould is partly immersed in the plastic

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solution such as to first allow a topside of the mould to come in contact with the solution (6:1-26). Note that the partial dip may be the first dip in a dipping process.

In a third interpretation under 35 USC 103(a) where the “topside” is interpreted to be some other portion of the mold than the flattened portion placed against the patient’s chest, Bellin teaches that it is known to form textures on other portions of the implants (see 1:5-65). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to provide the full or textured partial coating of Bellin by the processes described above on other portions of the implant in order to reduce slippage between the implant and other portions of the capsule (8:64-9:11).

3. **Claim 6** is rejected under 35 U.S.C. 102(b) as anticipated by Curtis (EP 0416846 A2). The rejection over Bellin under 35 USC 102(e) above appears likely to be antedated by a declaration under 37 CFR 1.131. Therefore, this additional rejection is also made. **As to Claim 6**, Curtis teaches a method for manufacturing a silicone cover (5:10-15), or article which could be used as a cover, for a breast implant (Abstract), wherein a mould for this cover (Fig. 1) is repeatedly dipped in a plastic solution (3:50-56), and after repeated dipping of the mould (3:50-56), at least one curing treatment takes place (4:29-43) wherein prior to said repeated dipping the mould is partly immersed in the plastic solution such as to first allow a topside of the mould (Fig. 1, item 10) to come in contact with the solution. It is submitted that partly immersing necessarily and inherently precedes full immersion or dipping (3:40-56), and that the tip of the mold facing the bath (item 10, Fig. 1) is inherently functions as a “topside” because the orientation of the

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article is arbitrary and the portion which faces the bath could be placed upwardly after removal from the form.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claim 7 is** rejected under 35 U.S.C. 103(a) as obvious over Bellin (USPN 6692527) in view of Van Aken Redinger (USPN 4455691). Bellin teaches the subject matter of Claim 6 above under 35 USC 102(e), or in the alternative, under 35 USC 103(a). **As to Claim 7**, Bellin teaches that solvent is evaporated (2:51-67) and heating at elevated temperature to cure (6:43-65). Although Bellin does not explicitly teach that the heated curing process evaporates solvent, it is submitted that some solvent would have obviously remained after the repeated dipping steps in view of Bellin's disclosure that each layer at least partially stabilizes (5:35-50). The solvent remaining in the partially stabilized layers would inherently evaporate during the initial stage of the curing process. In the alternative, Van Aken Redinger teaches dipping a form in a silicone dispersion (5:3-29) and evaporation after each layer at an elevated temperature (8:37-40). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method of Van Aken Redinger into that of Bellin in order to (a) increase the speed of the process by heating the article to remove solvent more rapidly, and (b) remove all trace of the solvent in order to avoid absorption by the patient.

5. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Curtis (EP 0416846 A2) in view of Van Aken Redinger (USPN 4455691). Curtis teaches the subject matter of Claim 6 above under 35 USC 102(b). **As to Claim 7**, Curtis is silent to the elevated temperature solvent evaporation. However, Van Aken Redinger teaches dipping a form in a silicone dispersion (5:3-29) and evaporation after each layer at an elevated temperature (8:37-40). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method of Van Aken Redinger into that of Curtis in order to (a) increase the speed of the process by heating the article to remove solvent more rapidly, and (b) remove all trace of the solvent in order to avoid absorption by the patient.

#### ***Response to Arguments***

6. Applicant's arguments filed 17 January 2008 have been fully considered but they are not persuasive. The arguments are on the following grounds:

- a) The rejections over Bellin must fall in view of the prior invention by Applicant.
- b) Nowhere does Curtis teach partly immersing and first allowing the topside of the mould to come into contact with the solution.

7. These arguments are not persuasive for the following reasons:

- a) See the response above regarding the declaration under 37 CFR 1.131. It is also noted that most or all of the evidence relied upon is between the Inventor and persons unrelated to this application. If it is asserted that these documents necessarily provide evidence of the conception



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and/or reduction to practice of the claimed invention, then it is unclear why these letters and other correspondence do not fall within the public use bar under 35 USC 102(b). The test for public use includes consideration of evidence relevant to experimentation, but also to public access to the use and confidentiality obligations imposed on members of the public (or other companies) who observed the use.

b) The application does not appear to set forth what is the “topside” of the mold, and it is asserted that any side may be interpreted as the topside. Also note that all that is required by the claim is that the “topside” of the mould must come into contact with the solution. The claim does not preclude subsequent full immersion, nor does it recite that a partial layer of material is formed over only a portion of the article. It is submitted that the Curtis process necessarily provides the limitations now claimed.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. DANIELS whose telephone number is (571)272-2450. The examiner can normally be reached on Monday - Friday, 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Matthew J. Daniels/  
Primary Examiner, Art Unit 1791  
4/17/08